Proposed Civil Money Penalty Calculation Methodology

Version II

Medicare Parts C and D Oversight and Enforcement Group

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Civil Money Penalty Calculation Methodology

I. Introduction

On December 15, 2016, the Centers for Medicare & Medicaid Services (CMS) released the final Civil Money Penalty (CMP) methodology for calculating Civil Money Penalties (CMPs) for (Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs) (hereinafter referred to as "sponsors") starting with referrals received in 2017. CMS stated that if the methodology is revised, CMS will publish any proposed changes in advance of implementation and provide the opportunity to comment. The methodology discussed in this document is the approach that CMS is proposing to use when calculating CMPs beginning in Contract Year (CY) 2019. CMS intends to apply this methodology to CMPs issued starting with referrals received in CY 2019 and beyond, so long as CMS does not modify the methodology. Once a revised methodology is finalized, CMS intends to apply it to audits, routine monitoring, surveillance activities, or identification of significant instances of non-compliance that occur in the contract year following publication. CMS is also applying this new methodology to Medicare Medicaid Plans (MMPs), Medicare Cost Plans, and Program of All Inclusive Care for the Elderly (PACE) Organizations. The methodology described in this document does not limit CMS' authority to impose any penalty that is permissible under the law.

II. Background

The Medicare Parts C and D Oversight and Enforcement Group (MOEG) evaluates referrals for potential enforcement actions, determines if enforcement actions are warranted, and imposes enforcement actions against sponsors when necessary. As discussed in the Authority section below, CMS' enforcement actions include issuing CMPs, imposing intermediate sanctions (suspension of marketing, enrollment, and/or payment), or terminating contracts.

Referrals for enforcement actions are based on non-compliance detected through routine audits, ad hoc audits, routine monitoring and surveillance activities, and the identification of significant instances of non-compliance. CMS used the published methodology to also calculate CMPs that resulted from other audits and monitoring activities, such as one-third financial audits, independent review entity (IRE) outlier monitoring activities, and plan benefit monitoring activities (e.g., Annual Notice of Change (ANOC)). Therefore, the methodology discussed in this document will be used to determine the calculations for most enforcement referrals received by MOEG. MOEG, however, reserves the right to use a different methodology as permitted by law depending on various circumstances. If a different methodology is applied, CMS will follow the principles outlined in this document as much as practicable.

In 2016, CMS published its CMP methodology in an effort to increase industry compliance and transparency. Since the methodology's release, CMS has continued to see improved compliance and audit performance. CMS proposes to update the methodology by adding an aggravating factor to encourage better compliance with CMS' rules, and removing the aggravating factor for a violation that is a top common condition listed in the annual Part C and D Program Audit and Enforcement Report. CMS also proposes increasing the per enrollee CMP penalty amounts. The HPMS memorandum that accompanies this document provides details on the proposed changes.

III. Authority to Issue CMPs

CMS' ability to issue CMPs derives from its authority to either terminate sponsors under 42 C.F.R §§ 422.510 and 423.509, or sanction sponsors under §§ 422.750, 422.752, 423.750, and 423.752. In lieu of, or in addition to, terminating a contract or issuing sanctions, CMPs can be imposed under §§ 422.752(b) and (c), and 423.752(b) and (c). Because CMPs have been historically issued under termination authority, the CMP methodology discussed in this document relates to that authority.

Pursuant to §§ 422.752(c) and 423.752(c), a CMP can be imposed on a sponsor for any of the criteria under the termination authority in §§ 422.510(a)(1)-(3), and 423.509(a)(1)-(3). The criteria include the sponsor:

1. Failed to substantially carry out the contract;
2. Is carrying out the contract in a manner inconsistent with the efficient and effective administration of 42 C.F.R. parts 422 or 423; or
3. Is no longer substantially meeting the applicable conditions of 42 C.F.R parts 422 or 423.

CMS may determine that one of the three criteria has been met when, for example, a sponsor substantially failed to comply with the requirements of Subparts M or V of 42 C.F.R. Parts 422 or 423 (see §§ 422.510(a)(4)(ii)-(xii) and 423.509(a)(4)(ii)-(xi) for examples of bases that may lead to a determination that one of the three criteria above has been met). Once a determination has been made that a sponsor's deficiency meets the requirements for a CMP, the penalty amount is calculated.

CMS is receiving referrals more frequently for MMPs, Medicare Cost Plans and PACE organizations, and has imposed enforcement actions for these violations when appropriate. For MMPs and Medicare Cost Plans, the bases for imposing enforcement actions are the same as MAOs and PDPs, as provided in the MMP contract and 42 C.F.R. §417.500, respectively.[1] As for PACE organizations, the bases for imposing enforcement actions is found at 42 C.F.R. §460.40 and 460.46.

IV. Calculation of the CMP Amount

CMS will calculate the CMP amount for each deficiency by applying a standard formula. Under the standard formula, CMS will apply a standard penalty amount (based on whether the deficiency should be calculated on a per enrollee or per determination basis) to the deficiency, and will adjust it for any factors that contributed to the deficiency (i.e., aggravating factors). If a penalty for a deficiency is calculated on a per enrollee basis, the penalty amount will be multiplied by the number of affected enrollees. If the penalty for a deficiency is calculated on a per determination basis, the penalty amount will be multiplied by the number of affected contracts. The total penalty amount will be limited for each deficiency if the sponsor's

[1] Although the bases for imposing enforcement actions is the same for Medicare Cost Plans, the calculation of penalties differs from MAO and PDP regulations. This will be discussed in more detail later in the methodology.

enrollment exceeds specific thresholds. Each of these concepts are discussed more thoroughly below.

CMS considers all of the facts and circumstances that led to a deficiency when determining if a CMP is warranted for the deficiency, including the type of benefit that was involved and whether CMS' guidance or systems may have contributed to the deficiency. Sponsors should submit evidence that potentially mitigates a deficiency to the CMS component that detected the deficiency. For example, if a deficiency was detected by CMS during a routine program audit, the sponsor should submit the mitigating evidence to CMS in response to the Draft Audit Report. CMS auditors will consider the information and may rely on it to justify removing the condition from the Final Report. If the deficiency is included in the Final Audit Report, CMS will consider the sponsor's responses to the Draft Audit Report when determining whether the deficiency warrants a CMP or other enforcement action.

A. Per Enrollee or Per Determination

Pursuant to 42 C.F.R. §§ 422.760(b)(1) and (2), 423.760(b)(1) and (2), 417.500(c), and 460.46, CMS determines if the penalty for a deficiency should be calculated on a per enrollee or per determination basis. Per enrollee deficiencies have a quantifiable number of enrollees that have been adversely affected (or have the substantial likelihood of being adversely affected), while per determination deficiencies do not have a quantifiable number of enrollees adversely affected. CMS will calculate the CMP amount for a condition on a per enrollee basis when the sponsor has provided CMS with an enrollee universe or Impact Analysis (IA) for the condition. The penalty and any aggravating factors will be applied only to affected enrollees identified in the universe or IA provided by the sponsor. If CMS does not have the enrollee-specific data or the per enrollee impact cannot be clearly analyzed, it will calculate the penalty under the per determination methodology. Please note that CMS may choose to impose a per determination penalty for a violation when the sponsor has provided CMS with an IA and CMS determines that enrollees were adversely affected by the violation. Under the per determination methodology, a penalty may be imposed for each deficiency, and the penalties will be imposed at the contract level (i.e., sponsors with multiple contracts may receive per determination penalties for each contract affected by a given deficiency).

B. Beneficiary Impact

If CMS determines that at least one beneficiary was adversely affected (i.e., directly adversely affected or substantially likely to have been adversely affected) by a sponsor's deficiency, a CMP can be issued under the termination authority.

CMS will rely on the data that are available at the time of the audit to determine if a sponsor's deficiency either directly adversely affected or had the substantial likelihood of adversely affecting an enrollee. A sponsor's deficiency could adversely affect an enrollee physically (e.g., adverse effects as a result of not receiving a medication or service or experiencing delayed access to a medication), affect an enrollee's rights (e.g. enrollees access to the appeals process is impeded), or affect an enrollee financially (e.g., by incorrectly denying claims from providers that result in inappropriate billing).

CMS will apply the "adversely affected" and "substantial likelihood of adversely affecting" standards judicially. CMS will issue a CMP under the adversely affected standard when it determines that an enrollee was directly adversely affected by a sponsor's deficiency. CMS also has the authority to determine that a sponsor's deficiency had the potential to adversely affect an enrollee even when a sponsor may be able to subsequently show, for example, evidence of a paid claim for the enrollee because the sponsor's violation could have adversely affected the enrollee (e.g., enrollees were delayed access to a medication or services).

When determining the number of enrollees "adversely affected", CMS will take into consideration whether the sponsor substantially mitigated the adverse impact to beneficiaries. CMS may remove those beneficiaries whose adverse impact is substantially mitigated (e.g., when the beneficiary receives his/her medication within one day of the initial rejection).

C. Amount of the CMP

Under §§ 422.760(b)(1) and (2), 423.760(b)(1) and (2), 417.500(c), and 460.46(a)(4), CMS has the authority to issue a CMP up to the maximum amount permitted under regulation, as adjusted annually[2] for each affected enrollee or per determination. However, CMS does not apply the maximum penalty amount in all instances because it believes the penalty amounts under the current methodology are sufficient to encourage compliance with CMS' rules. As more sponsors improve their performance, the CMP methodology may be revised to encourage any non-compliant sponsors to improve their performance. Before any revisions are made to the CMP methodology, CMS will publish the proposed changes in advance of implementation and provide an opportunity to comment.

The specific penalty amounts applied by CMS are discussed below.

1. Standard Penalty Amounts[3]

The standard penalty amount is based on the calculation type that is applied (i.e., per enrollee or per determination) and the type of adverse impact that occurred.

[2] Per the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, the maximum monetary penalty amount applicable to 42 C.F.R. §§ 422.760(b), 423.760(b), and 460.46(a)(4) will be published annually in 45 C.F.R. part 102. Pursuant to 42 C.F.R. § 417.500(c), the amounts of civil money penalties that can be imposed for Medicare Cost Plans are governed by section 1876(i)(6)(B) and (C) of the Social Security Act, not by the provisions in Part 422. Section 1876 solely references per determination calculations for Medicare Cost Plans. Therefore, the maximum monetary penalty amount applicable is the same as § 422.760(b)(1).

[3] Per enrollee amounts reflected here utilize the one proposed approach for adjusting per enrollee penalty amounts as outlined in the HPMS memorandum. CMS will release the final per enrollee amounts in the final 2019 CMP Methodology.

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Per Enrollee Penalties

- Inappropriate delay/denial of Part C medical services, Part D drugs, and/or appeal rights: $212 per enrollee
- Incorrect premiums charged or unnecessary costs incurred: $212 per enrollee
- Inaccurate or untimely plan benefit information (e.g., ANOC documents) provided: $27 per enrollee

Per Determination Penalties

- Invalid data submission (i.e., a plan sponsor's inability to track and provide data necessary to maintain and demonstrate compliant operations that could otherwise adversely affect beneficiaries): CMS will apply the maximum amount permitted under regulation, as adjusted annually,[4] per violation/per contract
- PACE violations: CMS will apply up to the maximum amount permitted under regulation, as adjusted annually,[5] per violation/per contract
- Medicare Cost Plan violations: CMS will apply up to the maximum amount permitted under regulation, as adjusted annually,[6] per violation/per contract
- All other violations: $20,000 per violation/per contract

2. Aggravating Penalty Amounts

Once CMS has calculated the standard penalty amount, it will apply any aggravating factors to it. Aggravating factors will increase the standard penalty amount.

a. Per Enrollee Aggravating Factors

Inappropriate delay/denial of Part C medical services, Part D drugs, and/or appeal rights

- Delay/denial of drugs that generally require access within one day in order to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions:[7] $106
- Prior offense:[8] $106 (one prior offense) or $1,000 (two or more prior offenses)
- Missed adjudication time requirement for expedited coverage decisions: $106
- Enrollees never received their Part C medical service or Part D medication: $106

Incorrect premiums charged or unnecessary costs incurred

- Incurred inappropriate out-of-pocket expenses exceeding $100: $106
- Prior offense: $106 (one prior offense) or $1,000 (two or more prior offenses)

[4] See footnote 2.
[5] See footnote 2.
[6] See footnote 2.
[7] CMS will carefully review each drug listed in sponsors' impact analyses to determine if it would have met the aggravating factor criteria when the deficiency occurred.
[8] CMS will apply the prior offense aggravating factor when it determines that the sponsor received the same finding in the preceding two calendar years. The finding can be cited in a previous compliance notice, audit report, or other enforcement action.

Untimely or inaccurate plan benefit information provided:

- Prior Offense: $16 for each prior offense
- For Annual Notice of Change (ANOC) documents: Enrollees did not receive ANOC/errata documents by Dec. 31: $16

b. Per Determination Aggravating Factors[9]

- Prior offense: $5,000

3. CMP Calculation Formulas

CMPs will be calculated using the following formulas:

- Per Enrollee:

Standard Penalty X *Number of Enrollees*
+
Aggravating factor(s) X *Number of Enrollees*
Total Penalty for the Violation

- Per Determination:

Standard Penalty X *Number of Contracts*[10]
+
Aggravating factor(s) X *Number of Contracts*
Total Penalty for the Violation

4. Maximum Penalty Amount

a. Enrollment-Based Limit

The CMP amount for each violation is restricted by the application of enrollment-based limits. The following limits apply to per enrollee penalties:

Enrollment of Parent Organization	CMP Violation Limit	Percent of Enrollment	Percent of Sponsors
Below 1,000	$50,000	0.1%	38%
1,000-4,999	$100,000	0.3%	16%
5,000-19,999	$200,000	1.2%	16%
20,000-49,999	$300,000	2.8%	13%
50,000-99,999	$400,000	2.7%	6%
100,000-249,999	$500,000	7.1%	7%
250,000-499,999	$1,000,000	2.6%	1%
500,000-2,999,999	$1,500,000	16.5%	2%
3,000,000 or more	$2,000,000	66.7%	1%

[9] The penalty amounts will be adjusted to align with Section 4(b) of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act). See footnote 2.

[10] The total number of contracts that were impacted by the deficiency.

b. Per Determination Limit

Pursuant to §§ 422.760(b)(1) and (2), 423.760(b)(1) and (2), 417.500(c), and 460.46(a)(4), as adjusted annually under 45 C.F.R. part 102,[11] CMS will apply the maximum penalty permissible when calculating a per determination penalty for a single deficiency and will apply that amount to all of a sponsor's contracts that are affected by the deficiency. The most recently published[12] maximum penalty amount that CMS will be permitted to apply under statute and regulation is $38,159[13] per determination. Thus, for example, if CMS determines that a deficiency is applicable to 10 of a sponsor's contracts, the maximum CMP that can be imposed for the determination in 2018 is $381,590.

[11] See footnote 2
[12] See footnote 2
[13] See footnote 2

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Appendix

Examples of CMP Calculations for a Sponsor with 300,000 Enrollees

Example 1: CMP Calculated on a Per-Enrollee Basis

- ***Standard Penalty***
  - Inappropriate delay/denial of Part D drugs, Part C services, and/or appeal rights: $212
  - Number of affected enrollees: 2,000
  - Standard penalty subtotal**: $424,000**

- ***Aggravating Factor #1***
  - Prior offense: $106
  - Number of affected enrollees: 2,000
  - Penalty adjustment**: $212,000**

- ***Aggravating Factor #2***
  - Delay/denial of Part D drugs that generally require access within one day in order to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions: $106
  - Number of affected enrollees: 500
  - Penalty adjustment: **$53,000**

- ***Total CMP Amount: $689,000 ($424,000 + $212,000 + $53,000)***

Example 2: CMP Calculated on a Per-Enrollee Basis and Application of the Enrollment-Based Limit

- ***Standard Penalty***
  - Inappropriate delay/denial of Part C medical services, Part D drugs, and/or appeal rights: $212
  - Number of affected enrollees: 6,000
  - Standard penalty subtotal: **$1,272,000**

- ***Aggravating Factor #1***
  - Prior offense: $106
  - Number of affected enrollees: 6,000
  - Penalty adjustment: **$636,000**

- ***Aggravating Factor #2***
  - Delay/denial of Part D drugs that generally require access within one day in order to either treat acute conditions or maintain the therapeutic treatment of non-acute conditions: $106
  - Number of affected enrollees: 1,580
  - Penalty adjustment: **$167,480**

- ***Penalty exceeds enrollment-based penalty maximum***
  - Penalty adjustment: **($1,075,480)**

- ***Total CMP Amount: $1,000,000 ($1,272,000 + $636,000 + $167,480 - $1,075,480)***

Example 3: CMP Calculated on a Per-Determination Basis for IDS condition

- ***Standard Penalty***
  - Sponsor failed to track organization determination receipt dates and therefore could not demonstrate to CMS that it was making decisions or providing notice to beneficiaries within required timeframes[14]: $38,159
  - Number of affected contracts: 15
  - Standard penalty subtotal**: $572,385**

- ***Total CMP Amount:* $572,385**

Example of a CMP Calculation for a PACE Organization

Example 4: CMP Calculated on a Per-Determination Basis for PACE violation

- ***Standard Penalty***
  - PACE violation – Sponsor failed substantially to provide participants with medically necessary items and covered PACE services, which adversely affected (or had the substantial likelihood of adversely affecting) participants[15]: $38,159
  - Number of affected contracts: 1
  - Standard penalty subtotal: **$38,159**

- ***Total CMP Amount:* $38,159**

[14] See footnote 2.
[15] See footnote 2.